REUTERS

FOCUS-Mentor denies FDA probe linked to irregularities

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(updates throughout with background, details, stock activity)

SANTA BARBARA, Calif. (Reuters) - Mentor Corp. one of the biggest manufacturers of saline-filled breast implants, on Thursday denied a published report that a Food and Drug Administration investigation is linked to irregularities in breast implant studies.

Shares in Santa Barbara, California-based Mentor rebounded sharply after the company issued its statement around midday, having tumbled by as much as 50 percent at the open before trading was halted.

Mentor shares were down 4-5/16 to 29-3/4 at 2:01 p.m. CST in brisk trading. Trading in the stock options was active as well, as traders panicked about news of an investigation and then ran for cover after the company issued its statement.

Responding to a USA Today article, Mentor said in a press release, that the FDA ``confirmed that there is an investigation stemming from 1998 manufacturing issues."

But the company said it is unaware and the FDA denied that the investigation ``has any connection whatsoever with 'allegations of serious irregularities in breast implant studies' as quoted by USA Today."

``We have complete confidence in the integrity of our research and believe that the allegations in the article are entirely baseless," said Anthony Gette, president and chief executive officer.

Gette said that since 1998, Mentor has substantially upgraded every aspect of its manufacturing facilities as well as its compliance programs.

Mentor has had two independent expert audits and one comprehensive FDA audit that have confirmed that the company is in ``substantial compliance" with good manufacturing practices, he said.

The company could not be reached to comment further.

Late last week, Rep. Tim Bliley, a Virginia Republican, chairman of the House Commerce Committee that oversees the FDA, asked the agency last week why the company was allowed to appear before an FDA panel considering the safety and effectiveness of saline-filled breast implants earlier this month even though the company was under investigation.

The FDA advisory panel on March 1 recommended the FDA officially approve saline implants made by Mentor and keep them on the market as long as certain conditions were met. It made its recommendation after reviewing industry-funded research.

Mentor shares have been on the rise ever since the key recommendation, rising to a fresh 52-week high on Wednesday.

While Bliley's March 17 letter didn't name Mentor specifically, a spokesman for his office confirmed Mentor was the subject of the FDA investigation.

The FDA declined to comment.

Bliley's spokesman said the FDA had not yet responded to the letter.

``The FDA appears to be doing a Dr. Jeckyl and Mr. Hyde act," he said. ``The (FDA) panel makes a recommendation and at the same time the credibility of the same company is in question by the FDA's own office."

The FDA panel earlier this month also said that saline implants made by Inamed Corp.'s McGhan Medical unit were safe and effective.

Mentor and McGhan are the two biggest makers of saline implants, each holding about 50 percent of the U.S. market for breast implants.

((Debra Sherman, Chicago Equities News at 312 408 8787, chicago.equities.newsroom+reuters.com))

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